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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/714,093	11/16/2000	Frank Butaric	CRD-834	5116

7590

11/04/2003

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EXAMINER

MILLER, CHERYL L

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 11/04/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/714,093

Applicant(s)

BUTARIC ET AL.

Examiner

Cheryl Miller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 16,17.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-5 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 1 recites, "the proximal open end of the stent is exposed to the body vessel." Applicant has positively claimed a portion of the body (body vessel), which is non-statutory subject matter. It is suggested to incorporate language such as "configured to" or "shaped to" or "adapted to" in order to overcome this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 3-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Edwin et al. (USPN 6,547,814 B2). Edwin discloses a radially expandable stent (46) having proximal and distal open ends and a longitudinal axis between (fig.4), the stent deployable in a body vessel,

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the stent comprising a plurality of hoops comprising a plurality of interconnected struts forming a substantially diamond shaped pattern (flared end hoops have diamond pattern, see fig.4; col.12, lines 55-56), the stent having a proximal and a distal hoop, the end hoops configured to have greater radial and longitudinal strength than the hoops between (the diamond end hoops are shown in fig.4 to be of a different size, larger than the middle diamond hoops, therefore are *configured* to have greater radial and longitudinal strength), a plurality of sinusoidal rings (struts 48 connecting diamond hoops) connecting adjacent hoops, the rings being formed from a plurality of alternating struts, and a junction of the alternating ring struts and a junction of the hoop struts being a common junction (fig.4), and proximal and distal attachment devices (adhesive or a second graft function as an attachment device to attach the stent to a graft, col.8, lines 35-59), the proximal attachment device positioned distal of the proximal open end, such that the proximal open end of the stent is exposed to the body vessel (fig.4).

Referring to claims 3-4, Edwin discloses a self-expanding stent, made of superelastic nickel titanium (col.6, lines 49-57; col.7, lines 5, 11-12).

Referring to claim 5, Edwin discloses an end hoop having a larger diameter than an adjacent hoop (fig.4; col.7, lines 1-2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1 and 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berry et al. (USPN 6,231,598 B1, cited in previous office action) in view of Freidberg (USPN 6,468,300 B1). Berry discloses a radially expandable stent (see figures 15, 16, 17, 18, and 20; col.8, lines 36-39) having proximal and distal open ends and a longitudinal axis between, the stent deployable in a body vessel, the stent comprising a plurality of hoops (13) comprising a plurality of interconnected struts (14) forming a substantially diamond shaped pattern (figs.15, 16, 17), the stent having a proximal (63) and a distal hoop (63'), the end hoops configured to have greater radial and longitudinal strength than the hoops between (col.17, lines 22-25), a plurality of sinusoidal rings (75, 108, 21) connecting adjacent hoops (col.9, lines 1-3; col.10, lines 26-32), the rings being formed from a plurality of alternating struts, and a junction of the alternating ring struts and a junction of the hoop struts being a common junction (36, 68; see figures 15, 17, 18). Berry does not disclose however, proximal and distal attachment devices and their location. Freidberg teaches in the same field of radially expandable stents, proximal and distal attachment devices (16) in order to attach a stent (12) to a graft (14), (col.2, lines 45-48), the proximal device (16) located distal the proximal end of the stent (fig.1), in order to expose the stent ends and preventing the graft from prolapsing at the ends (col.2, lines 42-48). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the stent structure of Berry with Freidberg's teaching of attachment devices and their location, for a stent, in order to attach a stent to a graft to increase support and biocompatibility, and expose the ends of the stent to provide support and prevent the graft from prolapsing into the ends of the stent.

Referring to claims 3-4, Berry discloses a self-expanding stent, made of superelastic nickel titanium (col.8, lines 60-63; col.18, lines 45-62).

Referring to claim 5, Berry discloses an end hoop having a larger diameter than an adjacent hoop (col.22, lines 1-7).

Claims 1 and 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berry et al. (USPN 6,231,598 B1, cited in previous office action) in view DeMarais et al. (USPN 6,355,057 B1, cited in previous office action). Berry discloses a radially expandable stent (see figures 15, 16, 17, 18, and 20; col.8, lines 36-39) having proximal and distal open ends and a longitudinal axis between, the stent deployable in a body vessel, the stent comprising a plurality of hoops (13) comprising a plurality of interconnected struts (14) forming a substantially diamond shaped pattern (figs.15, 16, 17), the stent having a proximal (63) and a distal hoop (63'), the end hoops configured to have greater radial and longitudinal strength than the hoops between (col.17, lines 22-25), a plurality of sinusoidal rings (75, 108, 21) connecting adjacent hoops (col.9, lines 1-3; col.10, lines 26-32), the rings being formed from a plurality of alternating struts, and a junction of the alternating ring struts and a junction of the hoop struts being a common junction (36, 68; see figures 15, 17, 18). Berry does not disclose however, proximal and distal attachment devices. DeMarais teaches a placement of proximal and distal attachment devices on radially expandable stents, specifically, the proximal attachment device positioned distal of the proximal open end (fig.3B, 4A; (60, 70); col.7, lines 10-18, 30-39, 51-53) such that the stent is exposed to the vessel (the entire stent is exposed when using an inner graft 18), for the purpose of securing a graft to the stent, the graft (col.5, lines 12-16; col.6), providing

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reinforcement and increased biocompatibility (col. 1, lines 29-37). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine DeMarais's teaching of stent attachment devices and their location, with the stent of Berry, in order to provide a means for attaching a stent to a graft, which provides reinforcement and increased biocompatibility.

Referring to claims 3-4, Berry discloses a self-expanding stent, made of superelastic nickel titanium (col. 8, lines 60-63; col. 18, lines 45-62).

Referring to claim 5, Berry discloses an end hoop having a larger diameter than an adjacent hoop (col. 22, lines 1-7).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

A handwritten signature in cursive script, appearing to read 'Cheryl Miller', is written in black ink.

Cheryl Miller

**BRUCE SNOW
PRIMARY EXAMINER**